

REMARKS

Claims 1-12, 14-16, and 30-35 are pending. No claims have been amended. All previous arguments and representations made regarding patentability are expressly withdrawn in favor of the remarks herein directed to the currently pending claims.

Rejections under 35 USC § 103(a):

Claims 1-12, 14-16, and 30-35 are rejected under 35 USC § 103(a) as obvious over Carpenter (US Pat. 4806343), Andya (US Pat. 6267958), Thomson (US Pat. 4816440), Nishimura (5861284), Arimura (US Pat. 5128242). Applicants traverse this rejection.

First, Nishimura and Arimura are cited by the Office as allegedly disclosing various protein formulations that may contain pituitary adenylate cyclase polypeptides. While this may or may not be correct, it is indisputable that neither of these references disclose **stabilized polypeptide particles**, as claimed in the present invention. Instead, these references disclose general lyophilization techniques with **no mention of producing particles** exclusively. Accordingly, these references fail to teach or suggest this claim limitation.

Second, while Carpenter, Andya, and Thomson are cited by the Office to remedy deficiencies of Nishimura and Arimura, the Office fails to supply sufficient motivation as to why these references would have been selected specifically for application to pituitary adenylate cyclase polypeptides. Applicants remind the Office that the Office imposed an election of species requirement on the Applicants, in response to which Applicants elected pituitary adenylate cyclase polypeptides. Accordingly, simply identifying **general polypeptide** handling materials and techniques does not address the motivation necessary to modify Nishimura or Arimura to arrive at the claimed stabilized **PACAP polypeptide** particles. The Office simply has not pointed out how, out of all of the possible materials and methods in the art, one of ordinary skill would have been motivated to pick out just those elements needed to create specifically the

elected and claimed stabilized PACAP polypeptide particles.

In fact, the only teaching that could have supplied the necessary motivation to combine Carpenter and Thomson with Nishimura, Arimura, and Andya comes from Applicants' disclosure. **Use of this teaching represents impermissible hindsight.**

The obviousness rejection made by the Office fails to address all of the claim elements, and fails to provide suitable motivation to modify the cited references to arrive at the claimed and elected invention. Either of these failures is sufficient to find that the rejections made by the Office do not satisfy the requirements of a *prima facie* case of obviousness. Accordingly, Applicants request the withdrawal of the rejection of claims 1-12, 14-16, and 30-35 under 35 USC § 103(a) as obvious over Carpenter (US Pat. 4806343), Andya (US Pat. 6267958), Thomson (US Pat. 4816440), Nishimura (5861284), Arimura (US Pat. 5128242).

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 777-4914.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **53-1953**.

Respectfully submitted,

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